NNMC Research Privacy Application
Preparatory to Research

Principal Investigator: **Department:**

Email address:

Phone number:

Research Staff needing access to protected health information:

Study Title or Study Idea:

Number of records needed: _____

The Privacy Rule (45 CFR 164.512) allows the use or disclosure of protected health information required in order to prepare a research application or proposal, provided that certain criteria are met. Please read the following statements. **If you agree, please sign below**. Also complete item #4.

1. The use or disclosure requested will be limited to the preparation of a research protocol or for similar purposes preparatory to research.

2. No protected health information will be removed from the covered entity by the researcher in the course of the review.

3. The requested information constitutes the minimum necessary data to accomplish the goals of the research.

4. **Please attach a list of the selection criteria for records required** (e.g.; all asthmatics seen in the Asthma Clinic), the dates of the records required (e.g.; clinic visits from July 1,1998 through December 31 2000), and data fields required for the research.

I declare that the requested information constitutes the minimum necessary data to accomplish the goals of the research.

I agree that the protected health information will not be re-used or disclosed to any other person or entity, except as required by law, for the authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Regulation (45 CFR 164.512)

_____ _____

Principal Investigator's signature Date

_____

Printed Investigator's Name

DATA AND/OR RECORDS NEEDED FOR RESEARCH PROTOCOL

1. Selection Criteria (e.g.; asthmatics seen in Asthma Clinic)

2. Dates of required records: from ___/___/___ through ___/___/___

3. Data fields required (list fields required from an electronic data base, or list fields to be recorded from the paper record by the researcher)
   - Find out study eligibility (screening)
   - Data analysis of results
   - Study audit and oversight
   - Establish {tissue or data, blood sample, or DNA} repository
   - Other {Describe or list other purposes as appropriate from protocol}

4. Anticipated sources of information (**check all that apply**)

   ☐ Paper medical records
   Specific description of information we will collect: indicate the health information you will collect during the research and from medical records. Delete the items that do not pertain.
   - problem list
   - medication list
   - list of allergies
   - immunization records
   - most recent history
   - most recent discharge summary
   - lab results {describe the dates or types of lab tests you would like disclosed}
   - X-ray and imaging reports {describe the dates or types of x-rays or images you would like disclosed}
   - consultation reports from {please supply doctors' names}
   - entire record
   - other {please describe}

   ☐ Electronic files

   ☐ Other _____

☐ Approve ☐ Disapprove

_____ _____
IRB Chairperson's Signature Date